October 2015

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SUM OF YOUR PARTS: ARE THERE ADEQUATE REMEDIES FOR VICTIMS OF FRAUDULENT TISSUE AND ORGAN ACQUISITION?

Azza Jayaprakash

I. INTRODUCTION

It seems unthinkable to reduce a human being to the sum of his parts—his organs, tissue, and cells. It seems even more distasteful to quantify the value of these parts. However, these are the decisions that face health care providers, researchers, legislatures, and society as the market for human organs and tissue grows. This is not simply a matter of black market trade in organs for desperate (and well-connected) recipients. Recent cases have shown that respected biotechnology companies may also become involved in the illegal acquisition of cadavers or organs and tissue from patients who consent only to surgery or laboratory tests, not the use of their harvested tissue for scientific or commercial research by third parties.\(^1\) Once third parties acquire such tissue—perhaps without knowledge of its unsavory origins—current law allows them to profit from their research without surrendering any compensation to patients or their families.\(^2\)

What happens when a biotechnology company unknowingly develops new technology from fraudulently acquired organs? What remedies are available to the families of victims when this company makes a huge profit from this technology and the accompanying patents and licenses? These questions are not merely hypotheticals. In 2004, it was discovered that employees of the University of California at Los Angeles ("UCLA") Willed Body Program\(^3\) were dismembering donated cadavers and selling organs and other tissues to medical research companies.\(^4\) One of these companies was pharmaceutical

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2 Moore v. Regents of University of California, 51 Cal.3d 120, 159 (Cal. 1990) (quoting 1 Harper et al., THE LAW OF TORTS § 2.34, at 234 (2d ed. 1986)).
3 The Willed Body Program is a program through which cadavers are donated to medical schools for use in anatomy classes. UCLA Willed Body Program Fact Sheet, http://www.ucla.edu/willedbody/factsheet.html (last visited April 21, 2006).
4 Murr, supra note 1, at 42.
giant Johnson and Johnson. Most disturbing are allegations that UCLA administrators were not simply lax in their oversight, but knew and tacitly approved of this lucrative "tissue bazaar." Fortunately, this misconduct was discovered, but how many other cases go undetected or unreported? How many victims and families of victims exist? How have courts and legislatures responded to this dilemma? Victims and their families turning to the existing legal framework for protection may find only pale shelter under the current legal regime.

The legal community must search for new and better ways to deter and regulate such activities, and ensure just compensation for victims and families violated by those who fraudulently acquire organs and tissue. As researchers continue to push the frontiers of medical science, it will become even more critical to strike a balance between stronger legal scrutiny of transactions involving human organs and tissue and allowing biotechnology companies the freedom to develop lifesaving technologies without excess red tape.

This article will not consider the morality or economics of transactions involving organs and tissue. Rather, this article will confine itself to exploring past and present remedies available to victims and families of victims defrauded by improper organ acquisition. It will focus on several regimes: intellectual property law, tort law, property law, and business ethics. This article also seeks to expose conflicting views within these regimes, and propose new remedies for victims.

II. BACKGROUND: HISTORICAL LACK OF REMEDIES FOR ORGAN AND TISSUE THEFT

Historically, there have been very few causes of action available for the victims of fraudulent acquisition of organs. These claims are usually confined to mishandling of cadavers. In the past, families have had a cause of action for mishandling of cadavers under theories of negligence or negligent infliction of emotional distress. Some

5 Id.
states have specifically made cadaver tampering a tort, or created criminal penalties for tampering with tissues and organs. Minnesota, for instance, has created a cause of action for interference with the legal right to the possession of the corpse for purposes of preservation and burial. However, these statutes impose liability only on the person who directly mistreats or mishandles the organs, not to third parties who subsequently possess the organs. Furthermore, due to informed consent and liability waivers, hospitals often have limited or no liability regarding mishandling or misappropriation of organs and cadavers.

As a result, living patients have found even less legal support to recover damages when tissues and organs have been improperly acquired in a hospital setting. In the benchmark case, Moore v. Regents of California, the plaintiff was convinced by his doctor to have surgery under false pretenses so that his doctor could acquire the plaintiff's tissue for his own lucrative research. The Supreme Court of California found against the plaintiff, pointing to the public policy implications of allowing a patient to retain property rights in tissue removed during surgery. The Court thus concluded that organs removed during surgery should be considered abandoned property; accordingly, the plaintiff's conversion claim was unsuccessful because he had no property interest in his own cells. However, the court upheld the plaintiff's argument that the acquisition and use of his cells,

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12 See Mark S. Nadel & Caroline A. Nadel, Using Reciprocity To Motivate Organ Donations, 5 Yale J. Health Pol'y, L. & Ethics 293, 301 (2005) [hereinafter Nadel & Nadel]; Uniform Anatomical Gift Act § 11 (1987) (“a hospital, physician, surgeon, [coroner], [medical examiner], [local public health officer], enucleator, technician, or other person, who acts in accordance with this [Act] or with the applicable anatomical gift law of another state [or a foreign country] or attempts in good faith to do so is not liable for that act in a civil action or criminal proceeding.”).
13 Id. at 135 (“[i]n effect, what Moore is asking us to do is to impose a tort duty on scientists to investigate the consensual pedigree of each human cell sample used in research. To impose such a duty, which would affect medical research of importance to all of society, implicates policy concerns far removed from the traditional, two-party ownership disputes in which the law of conversion arose.”).
14 Id. at 153-54 (citing Judge Broussard’s dissenting opinion).
tissue, and other bodily substances was a breach of fiduciary duties on the part of his physician.\(^\text{15}\)

Even though *Moore* presented a partial victory for the plaintiff, many other controversies remained. Although it protected research from the legal hindrance of property disputes, was it fair to effectively strip patients of property interests in their own organs and tissue? What remedies remained other than breach of fiduciary interest after this case? Who should be held liable in such cases?

As to the last question, the court answered that there was no liability for conversion of tissues and cells distributed to third party researchers.\(^\text{16}\) Under the particular circumstances presented in *Moore*, the court held that if the treating physician disclosed economic and research interests that may affect his judgment, plaintiff could not support claims for breach of fiduciary duty or failure to obtain informed consent.\(^\text{17}\) However, third party defendants could be held vicariously liable based on the acts of the treating physician.\(^\text{18}\)

Although there was some disagreement over Moore’s holding on policy grounds, it was certainly a predictable extension of a long line of case precedent on property interests in cadavers.\(^\text{19}\) For example, in *Holsen v. Heritage Mutual Insurance*, the court held that there is no property interest in a cadaver.\(^\text{20}\) Furthermore, in *Ramirez v. Health Partners of South Arizona*, the court held that the common-law claim for negligent interference with a dead body does not extend to the organ donation context.\(^\text{21}\)

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\(^\text{15}\) *Id.* at 152-53 (citing Judge Broussard’s dissenting opinion).

\(^\text{16}\) *Id.* at 143.

\(^\text{17}\) *Moore*, 51 Cal. 3d at 147.

\(^\text{18}\) *Id.* at 147. See infra Part III.A.3.b.


III. CURRENT REMEDIES FOR FRAUDULENTLY ACQUIRED ORGANS AND TISSUE

A. Tort-Based Remedies

This section includes an in-depth discussion of the various available tort claims for fraudulently acquired organs and tissues, including conversion, breach of fiduciary duty, and negligence.

1. Conversion

In tort claims for the fraudulent acquisition of organs and tissues, the issue of whether a property interest exists in organs and tissues is a recurring barrier encountered by plaintiffs. Precedent establishing that plaintiffs have been unable to claim a property interest under tort law has dramatically impacted the damages that plaintiffs may recover. Case law suggests that plaintiffs may not recover damages under a theory of conversion based on a property interest in cadavers and organs. Indeed, conversion claims have often been rejected in the context of human organs and tissue in several jurisdictions, including the Moore v. Regents decision. However, a growing number of scholars are pushing for courts to rethink the holding in Moore. In United States v. Arora, a Maryland district court applied the tort of conversion to the misappropriation of human tissue lines, concluding

22 RESTATEMENT (SECOND) OF TORTS § 868 cmt. a (1979). In the absence of a conversion claim, patient's families must usually rely upon the tort claim called interference with dead bodies. Damages for this claim stem from injuries resulting from mental distress. Id.
23 Id. Although the basis of the tort claim interference with a dead body is a quasi-property interest in the body, the drafters of the Restatement did not consider corpses property because traditionally they can not be transferred or sold. Several courts have rejected conversion claims involving corpses. See Perry v. St. Francis Hosp. & Medical Center, 865 F.Supp. 724, 726, 728 (1994); Culpepper v. Pearl Street Bldg., 877 P.2d 877, 880-882, 884 (1994).
24 Moore, 51 Cal.3d at 147.
25 See generally Charlotte H. Harrison, Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue, 28 AM. J.L. & MED. 77 (2002) (exploring the financial discrepancy in human organ commerce and noting researchers and biomedical companies gross substantial profits from body products of human donors, but the donors rarely see any of these proceeds); Donna M. Gitter, Ownership Of Human Tissue: A Proposal For Federal Recognition Of Human Research Participants' Property Rights In Their Biological Material, 61 WASH. & LEE L. REV. 257, 270 (2004); see generally Jordan & Price, supra note 7, at 151.
that human cell lines are indeed property.\textsuperscript{26} In \textit{Hecht v. Superior Court}, the court held there was property interest in sperm for the purpose of inheritance.\textsuperscript{27} Unfortunately, these cases are the rare exception to the vast majority of cases which have held the opposite.\textsuperscript{28}

Assuming \textit{arguendo} that courts upheld such a conversion claim, third party beneficiaries may still avoid liability.\textsuperscript{28} Established conversion law permits a "subsequent innocent converter" to retain the financial benefit of work expended on the stolen property.\textsuperscript{29} As Moore demonstrates, medical researchers and drug manufacturers are free to reap the economic fruits of research from fraudulently acquired organs and cadavers.\textsuperscript{30}

\section*{2. Breach of Fiduciary Duty}

Breach of fiduciary duty provides another cause of action. However, the reach of such claims is limited as patients may only recover from defendants that are subject to a fiduciary duty, namely their own physicians.\textsuperscript{31} Patients may not recover from a biotechnology company or from a physician-researcher who is not treating the patient under this claim.\textsuperscript{32} Although third-party corporations might be liable under \textit{respondeat superior}, this view has been looked upon with considerable skepticism since it is often the case that a principal-agent relationship exists between physicians and corporate defendants.\textsuperscript{33}

Courts and scholars alike have acknowledged the dearth of remedies against third parties who benefit from the acquisition of organs.\textsuperscript{34} However, it is up to legislatures to remedy this void, since

\begin{itemize}
  \item \textsuperscript{26} United States v. Arora, 860 F. Supp. 1091 (D. Md. 1994), aff'd, 56 F.3d 62 (4th Cir. 1995).
  \item \textsuperscript{27} Hecht v. Superior Court, 16 Cal.App.4th 836, 20 Cal.Rptr.2d 275 (Cal. Ct. App. 1993) (holding that probate court held jurisdiction over decedent's property interest in his cryogenically preserved sperm).
  \item \textsuperscript{28} See Greenberg v. Miami Children's Hospital Research Institute, 264 F.Supp.2d 1064, 1074 (S.D. Fla. 2003) (refusing find a property interest for the body tissue and genetic information); Moore, 51 Cal.3d at 149; Perry, 886 F.Supp. at 1563; Culpepper, 877 P.2d at 883.
  \item \textsuperscript{29} Moore, 51 Cal.3d at 159 (citing Judge Broussard's dissenting opinion).
  \item \textsuperscript{30} \textit{Id.} (citing 1 Harper et al., THE LAW OF TORTS § 2.34, at 234 (2d ed. 1986)).
  \item \textsuperscript{31} \textit{Id.}
  \item \textsuperscript{32} \textit{Id.} at 133.
  \item \textsuperscript{33} \textit{Id.} at 181-182 (Mosk, J., dissenting).
  \item \textsuperscript{34} \textit{Id.} at 175 (Mosk, J., dissenting) (quoting Dr. Thomas H. Murray: "[i]f biotechnologists fail to make provision for a just sharing of profits with the person
our legal framework does not impose clearly-defined duties on pharmaceutical or biotechnology corporations for research on cadavers and organs.\(^{35}\)

3. Negligence

a) Negligence Claims For Failure to Inform

Although courts are far more willing to accept negligence claims than other tort claims for misappropriation and mishandling of organs and cadavers, there are several obstacles and restrictions that make it difficult for plaintiffs to recover damages. Plaintiffs must clear two hurdles to recover.\(^{36}\) First, plaintiffs must establish a *causal connection* between their injury and the physician's failure to inform.\(^{38}\) Specifically, plaintiffs must demonstrate that if they had been fully informed, they would have declined to consent to the procedure in question.

Second, plaintiff must also prove that *no reasonably prudent person* would have given consent had he been properly informed.\(^{37}\) Several jurisdictions focus on this stringent "objective" standard.\(^{38}\) Although this standard allows courts to avoid depending on the patient's biased and highly-subjective perspective on whether, in hindsight, they would have consented, this standard establishes a very heavy burden for plaintiffs to satisfy.\(^{39}\) Regardless, negligence claims for failure to inform do not extend to third party corporations that come into possession because they have no duty or other relationship with the victim.\(^{40}\)

whose gift made it possible, the public's sense of justice will be offended and no one will be the winner."\(^{37}\)

\(^{35}\) *Id.* at 178.

\(^{37}\) Moore, 51 Cal.3d at 179.

\(^{38}\) See *id.* at 179; Martin & Lagod, *Biotechnology and the Commercial Use of Human Cells: Toward an Organic View of Life and Technology*, 5 SANTA CLARA COMPUTER & HIGH TECH L.J. 211, 222 (1989); Cobbs v. Grant, 8 Cal.3d 229, 245 (Cal. 1978).

\(^{39}\) Cobbs, 8 Cal.3d. at 245.


\(^{40}\) See Moore, 51 Cal.3d at 133. Because corporations, as non-physician entities, have no fiduciary duty to patients, they may escape liability for breach of fiduciary duty. *Id.*
b) Vicarious Liability for Negligent Infliction of Emotional Distress

Plaintiffs may only recover for damages caused by emotional distress from anyone "who intentionally, recklessly or negligently removes, withholds, mutilates or operates upon the body of a dead person or prevents its proper interment or cremation."\(^4\) Lawmakers have purposefully avoided making this a property-based tort claim, as evidenced by the comments of drafters of the Second Restatement of Torts:

This [claim] does not, however, fit very well into the category of property, since the body ordinarily cannot be sold or transferred, has no utility and can be used only for the one purpose of interment or cremation. In practice the technical right has served as a mere peg upon which to hang damages for the mental distress inflicted upon the survivor; and in reality the cause of action has been exclusively one for the mental distress.\(^4\)

An essential element of negligence is that the defendant owes a duty of care to the plaintiff.\(^4\) Third party corporations often do not assume any duty related to patient services. It would therefore appear that corporations could escape liability for negligent infliction of emotion distress. However, plaintiffs may sue under the theory that a corporation negligently purchased human organs or should have known that the transaction violated federal and state laws that prohibit the sale of human organs.\(^4\)

In *Pool v. City of Oakland*, the court held that a defendant may be found liable where that defendant induced another to act in circumstances under which it was foreseeable that the conduct would cause injury to a third party.\(^4\) Similarly, in *Christensen v. Superior Court*, the court reasoned that "[i]f the likelihood that a third person

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\(^4\) *RESTATEMENT (SECOND) OF TORTS* § 868 cmt. a (1977).

\(^4\) *RESTATEMENT (SECOND) TORTS* § 4 cmt. b (1965) (discussing the definition of duty in the context of negligence).


\(^4\) See *Pool v. City of Oakland*, 42 Cal.3d 1051, 1073, 232, Cal.Rptr. 528, 728 P.2d 1163 (Cal. 1986).
may react in a particular manner is a hazard which makes the actor negligent, such reaction whether innocent or negligent does not prevent the actor from being liable for the harm caused thereby. Thus, plaintiffs may hold corporations vicariously liable on a theory that it encouraged or induced the unlawful conduct of another.

This joint enterprise theory is a well-established exception to the general rule that does not attribute liability for the negligence of another.

[B]efore the courts will find that the parties were joint adventurers there must be clear evidence of a community of interest in a common undertaking in which each participant has or exercises the right of equal or joint control and direction. A joint venture is sort of a mutual agency, akin to a limited partnership. It is not sufficient that the parties have certain plans in common, but the community of interest must be such that [each] is entitled to be heard in the control [of the enterprise]. Most of the cases indicate that the common interest must be of some business nature.

In Christensen v. Superior Court, the court examined whether a research company could reasonably foresee that its conduct in offering to buy substantial quantities of human organs and body parts from defendant crematory operators would induce those defendants to obtain the organs and body parts in a manner that causes extreme emotional distress to the decedent’s relatives. Accordingly, the court held that if the research company should have foreseen that the

46 Christensen, 54 Cal.3d at 892 (quoting Weirum v. RKO General, 15 Cal.3d 40, 47, 123 Cal.Rptr. 468, 539 P.2d 36 (Cal. 1975)). See also Clark v. Library of Congress, 750 F.2d 89, 98 (D.C. Cir. 1984) (where defendant induced violation of plaintiff’s civil rights).

47 Id. at 892 (citing 5 Harper et al., THE LAW OF TORTS § 26.1, at 3 (2d ed. 1986)); see RESTATEMENT (SECOND) OF TORTS § 302(b) (1965) ("[a]n act or an omission may be negligent if the actor realizes or should realize that it involves an unreasonable risk of harm to another through the conduct of the other or a third person which is intended to cause harm, even though such conduct is criminal.").


50 Christensen, 54 Cal.3d at 893.
crematory defendants would violate the law, then the research company would be found negligent per se.51

B. Remedies under Intellectual Property Law and Unjust Enrichment from Fraudulently Acquired Organs and Tissue

1. The Commoditization of Organs, Cells, and Tissues

As discussed above, the courts have been unwilling to view organs and tissue as property for the tort of conversion.52 However, in the context of organ donations, courts and legislatures have created property rights that do not otherwise exist.53 For instance, the Ohio Anatomical Gift Law suggests that the donor has a property right to her organs before death, which transfers to the donee upon the execution of the statutorily approved instruments or upon death.54 This conflict is observed in several state organ donation statutes.55 However, courts have refused to extend these property rights in the context of tort-based claims.56 Yet, biomedical and biotechnology companies heavily invest in human organs and tissue in order to obtain their own intellectual property rights.57 This conflict between regimes allows corporations to be

51 Id.
52 See Greenberg, 264 F.Supp.2d at 1074; Moore, 51 Cal.3d at 149; Perry, 886 F.Supp. at 1563; Culpepper, 877 P.2d at 880-882.
53 See GA. CODE ANN. § 44-5-145 (Georgia's anatomical gift act allows donees to transfer, escheat, and revoke anatomical gifts; see OHIO REV. CODE § 2108.02(f) (2003) (“donee has a property right in an anatomical gift donated”); OR. REV. STAT. § 97.954 (stating that the donee has the power to give or revoke an anatomical gift by written instrument); Whaley v. County of Tuscola, 58 F.3d 1111, cert. denied 116 S.Ct. 476, 516 U.S. 975, 133 L.Ed.2d 404 (6th Cir. 1995), on remand 941 F.Supp. 1483 (relatives had constitutionally protected property interest in corpse, under common law right to possess relative's body for the purposes of burial and to prevent mutilation of body and state Anatomical Gift Act, which gave relatives the right to make a gift of all or part of decedent's body).
55 See generally GA. CODE ANN. § 44-5-140 (instead of 140, article 6) (Georgia's anatomical gift act allows donees to transfer, escheat, and revoke anatomical gifts; see OHIO REV. CODE § 2108.02(f) (2003) (“donee has a property right in an anatomical gift donated”); OR. REV. STAT. § 97.954 (stating that the donee has the power to give or revoke an anatomical gift by written instrument).
56 Ramirez, 193 Ariz. at 333.
unjustly enriched from fraudulently acquired organs, while patients are unable to recover under traditional property law or patent law.\textsuperscript{58}

The United States Patent and Trademark Office ("USPTO") once barred the patenting of cells and tissue for many of the same policy reasons that prevent patients from having property rights in their organs.\textsuperscript{59} Currently, cells, DNA, and microorganisms are patentable if they have been genetically engineered or modified from their natural states.\textsuperscript{60}

The number of patents involving DNA, cells, and transplantation technology has grown astoundingly. Children's Hospital of Boston owns patents that cover growing organs \textit{in vivo}.\textsuperscript{61} The University of Missouri owns a patent that covers not simply cloning technology, but potentially a cloned human being.\textsuperscript{62} Another biotechnology company owns a patent which covers "stem cells containing a genetic sequence that allows the undifferentiated cells to be specifically eliminated, leaving the differentiated cells unaffected."\textsuperscript{63} The prevalence of this research is evidence of the common use of cell, tissues, and organs in research, and the tacit acceptance of this research by the USPTO. This tacit acceptance may

\textsuperscript{58} \textit{Id.} at 326 ("[t]issues may be harvested absent consent, and sometimes after denial."); \textit{Ramirez}, 193 Ariz. at 333; \textit{Moore}, 51 Cal.3d at 136-37 (plaintiff's cells were obtained by his physician under false pretenses and patented; however, plaintiff was not able to recover under a conversion claim, and had no remedy under patent law); \textit{but see} Christopher Scott Pennisi, \textit{More On Moore: A Novel Strategy For Compensating The Human Sources Of Patentable Cell-Line Inventions Based On Existing Law}, 11 \textit{FORDHAM INTELL. PROP. MEDIA & ENT. L.J.} 747, 750 (2001) (suggesting that patients whose cell lines have been used in the development of patented cell lines, may be compensated under patent law's shop right doctrine).

\textsuperscript{59} \textit{See} Diamond v. Chakrabarty, 447 U.S. 303 307-08, 100 S. Ct. 2204 (1980). In addition to statutory barriers, Courts often rejected the idea of patenting living creatures on moral and ethical grounds. \textit{Id.}

\textsuperscript{60} \textit{Chakrabarty}, 447 U.S. at 309-310; U.S. Patent No. 6,855,543 (issued February 15, 2005).

\textsuperscript{61} Virginia Baskerville, \textit{Patents Cover Technology to Grow Organs In Vivo}, \textit{TRANSPLANT NEWS NETWORK} (July 15, 1998), \texttt{available at} http://www.centerspan.org/tnn/98071504.htm (last visited April 22, 2006).

\textsuperscript{62} Kristen Philipkoski, \textit{Why Does School Own Clone Patent?}, \textit{WIRED NEWS} (May 16, 2002), \texttt{available at} http://www.wired.com/news/technology/0%2C1282%2C52610%2C00.html (last visited April 22, 2006); \textit{see also} U.S. Patent No. 6,211,429 (issued April 3, 2001).

\textsuperscript{63} Geron Receives U.S. Patent for Pluripotent Stem Cells Modified for Therapeutic Applications, \textit{BUSINESS WIRE} (June 10, 2003), \texttt{available at} http://www.mcpf.org/displayarticle.asp?articleId=174 (last visited April 22, 2006); \textit{see} U.S. Patent No. 6,800,480 (issued October 5, 2004).
perhaps encourages this research and further fuels the commoditization of cells, organs, and tissues. Unfortunately, despite technology flourishing in this field, the demand for organ transplants has well exceeded the supply. 64

Patent law provides inventors with a government-sponsored monopoly in these technologies and, at times, the cells and modified genetic materials themselves. Unfortunately, patent law does not provide many punitive measures or civil remedies for patent inventions developed using stolen biological materials. 65 Still, there are a few unconventional ways in which patients may attack the validity of such patents. 66

2. Constitutional Arguments for Invalidating Patents on Inventions Involving Genetic Materials

The Fourteenth Amendment grants citizens the power to control reproduction. 67 Patent applications are published, and all of the information therein is released to the public domain. 68 If the patent covers modified DNA, the public may have access to a portion of someone's DNA which could then be synthesized and propagated in a cell line. 69 Where an invention involves the propagation of fraudulently acquired organs, cells, and DNA, plaintiffs may argue that granting a patent will indirectly infringe on the plaintiff's Fourteenth Amendment reproductive rights because government approval of the patent makes it complicit in the release of genetic information in violation of the plaintiff's reproductive rights. 70

64 Nadel & Nadel, supra note 12, at 293.
65 Moore, 51 Cal.3d at 136-37 (plaintiff's cells were obtained by his physician under false pretenses and patented; Greenberg, 264 F.Supp.2d at 1074 (refusing to find a property interest for the body tissue and genetic information, where patients with the Canavan disease donated blood samples to researchers who discovered the Canavan gene, and then secretly patented and restricted the availability of testing).
66 For complete discussion see section B.2.
68 35 U.S.C § 122 (generally, all applications are published in the USPTO Gazette 18 months after filing).
70 Cf. Paul Lesko & Kevin Buckley, Attack Of The Clones ... And The Issues Of Clones, 3 COLUM. SCI. & TECH. L. REV. 1, 1 (2002) (discussing whether bans on cloning may be held unconstitutional on the ground that they infringe reproductive
Such a patent grant appears to violate the Due Process Clauses of both the Fifth and Fourteenth Amendments which prohibit state and federal governments from depriving an individual's "life, liberty or property without due process of law." The Fourteenth Amendment embraces the right to control reproduction. The Fourteenth amendment prohibits the government from compelling or facilitating the compulsion of reproduction. In turn, the right to control reproduction falls under the greater umbrella of the Fourteenth Amendment right to privacy. Thus, the release of a patient's genetic information infringes upon both the right to privacy and, potentially, the right to control reproduction.

3. The Tainted Research Doctrine

Another remedy lies in an equitable doctrine referred to by one scholar as the tainted research doctrine. The tainted research doctrine allows Courts to invalidate the patent for an invention that was the result of research involving theft, criminality, or scientific fraud. For example, if a plant is illegally acquired and a new drug or novel gene is isolated, developed, patented, and sold using this sample, the patent could be held unenforceable as the product of "tainted research." In Regents of the University of California v. Eli Lilly, university researchers violated
National Institutes of Health ("NIH") regulations prohibiting the use of uncertified plasmids in mammalian recombinant DNA research, and developed cDNA encoding human insulin using these plasmids.\(^{77}\) In their patent application, these researchers then falsely indicated that they had used a certified plasmid.\(^{78}\)

The lower court invalidated the patent on a theory of patent fraud.\(^{79}\) However, the appeals court reversed, concluding that the misstatements were not "material" to examination of the patent application.\(^{80}\) One scholar believes that the case teaches us that although inventions based on tainted research might result in a claim of fraud,\(^{81}\) a patent will only be unenforceable if misrepresentations are material to the inventor's patent application.\(^{82}\)

Although not generally accepted, the tainted research doctrine could be applied in the context of research involving fraudulently acquired tissue and organs if the USPTO considered the disclosure of the origin of genetic sources and biological samples "material" or required such information for patent applications.\(^{83}\) However, this would constitute a major paradigm shift in patent prosecution.\(^{84}\) Currently, patent applicants are not required to provide the origin of genetic resources, organs, or tissues.\(^{85}\) However, this could change as a result of the United Nations Convention for Biological Diversity.\(^{86}\)


The international intellectual property community has become increasingly alarmed at instances of biotechnology corporations that acquire and patent traditional knowledge from aboriginal cultures

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\(^{78}\) Id.

\(^{79}\) Id. at 1569.

\(^{80}\) Id. at 1571.

\(^{81}\) See Gollin, supra note 79.

\(^{82}\) 37 C.F.R. § 1.56 (stating that the inventor has a "duty to disclose to the [USPTO] all information known that individual to be material to patentability" (emphasis added)).

\(^{83}\) Gollin, supra note 79; 37 C.F.R. § 1.56 (listing all of information applicants must disclose).

\(^{84}\) 37 C.F.R. § 1.56. Although the USPTO requires disclosure of prior art, it does not require disclosure of genetic resources. Id.

\(^{85}\) Id.

\(^{86}\) See Gollin, supra note 79.
without providing just compensation or recognition for such knowledge.\textsuperscript{87} Scholars and the press often call this phenomenon "biopiracy."\textsuperscript{88} In 1993, the United Nations Convention on Biological Diversity ("CBD") was convened in order to open an international dialogue and facilitate treaties to prevent biopiracy.\textsuperscript{89} Currently, the USPTO does not require that applicants indicate the origin of genetic resources or biological material.\textsuperscript{90} However, it is common practice for natural product patents to identify the country from which biological material was obtained in order to satisfy the patent enablement requirement.\textsuperscript{91}

The European Parliament attempted to adopt a measure requiring patent applicants to disclose a biological material's geographical source.\textsuperscript{92} The European Commission eventually rejected the Parliament's proposal because it was more restrictive than the CBD requirements.\textsuperscript{93} However, if such a proposal were ever adopted, then nondisclosure of source country would invalidate the patent.\textsuperscript{94}

Under the proposed rules of the CBD, there are several consequences for misrepresentation of the origin of genetic materials, including weak patents; liability for profit sharing claims;\textsuperscript{95} consumer boycotts; barriers to importation of biotechnology products; and loss of market share.\textsuperscript{96}

Under the proposed CBD regulations, if a researcher illegally removes biological material from a source or source country and profits from this material, the source or source country could recover all or some of the profits based on a theory of misappropriation.\textsuperscript{97} Also, under the CBD, legal title to biological material can only be acquired if

\textsuperscript{87} Id.
\textsuperscript{89} Convention on Biological Diversity, June 5, 1992.
\textsuperscript{91} See Gollin, \textit{supra} note 79.
\textsuperscript{92} See id.
\textsuperscript{93} See id.
\textsuperscript{94} See id.
\textsuperscript{95} See id.
\textsuperscript{96} See Gollin, \textit{supra} note 79.
\textsuperscript{97} See id.
the sample was legitimately obtained with informed consent from a source. \(^9_8\) If there is no legal title, the collector of an illegitimate sample will not be able to legitimately transfer this sample to colleagues, partners, or third parties for experimentation. \(^9_9\) Moreover, if a supplier falsely declares under contract that it properly obtained a sample, then the recipient may collect damages for breach of contract from the person who collected the sample. \(^1_0^0\)

C. Remedies under the Racketeer Influenced and Corrupt Organizations Act

1. RICO Violations Stemming from Patent Fraud

If a corporation has developed and patented technology using misappropriated organs and tissues, the Racketeer Influenced and Corrupt Organizations ("RICO") Act may be another source of relief. \(^1_0^1\) RICO Act claims are not isolated to claims involving organized criminal activity \(^1_0^2\) Under the RICO Act, successful plaintiffs may collect treble damages and attorneys fees. \(^1_0^3\) If plaintiffs can establish that a corporation repeatedly participated in illegal commercial transactions involving organs, then those plaintiffs may recover under the RICO Act. \(^1_0^4\)

Civil RICO complaints have been filed based on mail or wire fraud, including cases involving patent fraud. \(^1_0^5\) The USPTO requires patent applicants to disclose all known documents relevant to earlier patents and publications concerning similar inventions. \(^1_0^6\) If a patent applicant fails to disclose relevant documents during the original examination, this may constitute patent fraud. \(^1_0^7\) Because patent applicants often send patent application documents to the USPTO via

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\(^9_8\) See id.
\(^9_9\) See id.
\(^1_0^0\) See id.
\(^1_0^1\) Steven Fasman, *The Proper Application Of Civil Rico To Patent Fraud*, 96 *Yale L.J.* 1323 (1987).
\(^1_0^3\) 18 U.S.C. § 1964(c).
\(^1_0^4\) See generally 18 U.S.C. § 3331.
\(^1_0^5\) Id.
\(^1_0^6\) Manual of Patent Examining Procedure § 1448; 37 CFR 1.56.
\(^1_0^7\) Id.
mail, patent fraud could be used to prove the mail fraud requirement under RICO.\textsuperscript{108}

Although RICO claims have rarely been upheld in the context of patent law, the Court sustained the plaintiff’s RICO claim based on the prolonged pattern of defendant’s misconduct in \textit{Lemelson v. Wung Labs}.\textsuperscript{109} However, if the USPTO adopts the CBD guidelines (discussed \textit{supra} in Part III.B.4) requiring the disclosure of the genetic resources’ and biological materials’ origins as a prerequisite for patent applications, this may open the door to many more patent fraud cases under the RICO Act.\textsuperscript{110}

2. RICO Claims Stemming from Illegal Transactions Involving Human Organs

In cases involving the fraudulent acquisition of cadavers and organs, RICO claims may be predicated on grounds other than patent fraud.\textsuperscript{111} The RICO Act defines racketeering as “any act which is indictable” under Title 18, sections 1957, 2314 and 2315.\textsuperscript{112} Section 1957 prohibits monetary transactions in property derived from specified unlawful activity.\textsuperscript{113} The National Organ Transplantation Act criminalizes human organ transactions, prohibiting anyone from knowingly acquiring, receiving, or otherwise transferring “any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.”\textsuperscript{114}

\begin{flushleft}
\footnotesize
\textsuperscript{108} Using mail to perpetrate a fraud is the predicate act required for mail fraud. \textit{See Greek}, \textit{supra} note 106.

Patent law requires those applying for a patent to collect and send to the patent office by mail all documents related to previous patents for similar inventions. Failure to provide such documents during the original examination can constitute fraud if the current patent holder can prove the admissibility and relevance of prior patents thought to be known to the applicant. Since the mails are used in the application process, patent fraud can be applied as the RICO predicate of mail fraud and triple damages plus attorney's fees sought.

\textit{Id.}


\textsuperscript{110} \textit{See Gollin}, \textit{supra} note 79 (discussing the CBD and patent disclosure requirements).

\textsuperscript{111} \textit{See} 18 U.S.C. § 1962.


\textsuperscript{113} 18 U.S.C. § 1957.

\textsuperscript{114} \textit{See National Organ Transplant Act}, 42 U.S.C. § 274e(a) (prohibiting the sale of human organs).
\end{flushleft}
Because Sections 2314 and 2315 prohibit interstate transportation of stolen property and the National Organ Transplantation Act prohibits interstate transactions involving organs, plaintiffs may be able to substantiate a RICO Act claim for the interstate sale of organs.\(^{115}\) In a RICO claim courts will need to determine whether organs can be considered property. In the interest of justice, the answer must be found in the state’s Organ Donation Acts, which vest patients and family members with a quasi-property interest in organs and cadavers.\(^{116}\)

D. BUSINESS ETHICS, SEC VIOLATIONS, AND THE POWER OF SHAREHOLDERS

1. Business Ethics

Corporate liability must also be viewed from the perspective of business ethics and policy. In the wake of the Enron scandal, there has been a new call for business ethics and corporate accountability.\(^{117}\) Shareholders and the public are demanding a greater amount of responsibility on the part of corporations.\(^{118}\) Accordingly, there must be more diligence in assuring that organs are legitimately acquired.\(^{119}\)

Both the government and the public expect and demand more from biotechnology corporations, premised on the prominent role they play in our health care system.\(^{120}\) These corporations have increased incentives for due diligence in the acquisition of organs,\(^{121}\) since failing to exercise due diligence in confirming the sources of organs and tissue\(^{122}\) may result

\(^{115}\) See 18 U.S.C. § 2314, 2315.

\(^{116}\) See generally Stickney, supra note 58.


\(^{118}\) See id.

\(^{119}\) See id.


\(^{121}\) See Gollin, supra note 79.

in millions of dollars in litigation costs and awards. Moreover, the loss of good will can be devastating to the financial viability of a company in the aftermath of such scandals.

2. Securities Fraud and Shareholders’ Derivative Suits

It is also important to acknowledge the power of shareholders in examining corporate liability and schemes to fraudulently acquire organs. This is not simply a crime against the victim and his family, it is a wrong perpetrated against society and, indirectly, shareholders. In 2003, shareholders of transplant company Cryolife filed a shareholders derivative suit, stemming from Cryolife’s mishandling of cadavers, which led to the deaths of heart valve and knee tissue transplant recipients. According to plaintiffs, Cryolife assured its shareholders and the investing public that “patient safety was its paramount concern” and that Cryolife was in compliance with FDA regulations. However, in one instance, a 23 year-old man who underwent elective knee surgery died as a result of an allograft; the allograft, which was manufactured and sold by Cryolife, had been contaminated with bacteria from the bowel of a cadaver donor.

The shareholders’ complaint alleges that defendants violated “Rules 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5…by issuing materially false and misleading statements regarding quality control problems in [Cryolife’s] processing of human
tissues and heart valves that had the effect of artificially inflating the market price of [Cryolife’s] securities.”

Plaintiffs allege that Cryolife knowingly made false statements, and “demonstrated a pattern of nondisclosure or severe reckless disregard with respect to its disclosures to shareholders and regulatory edict.” The shareholders seek damages for all persons and entities who purchased stocks between April 2, 2001 and August 14, 2002. As a result of this litigation, Cryolife’s image has been negatively impacted, and the company has incurred significant litigation fees. This may also set an important precedent for the power of shareholders to influence corporate policy on human tissue transactions.

3. Corporate Incentives to Comply with FDA Regulations and Statutes Regarding Handling of Cadavers and Organs

The consequences of mishandling cadavers are not restricted to lawsuits against the company. The most profound and devastating consequences may be the effect on investors’ confidence in the stocks of those companies. For instance, after a CDC investigation, Cryolife admitted in a press release that it gave a patient an infected heart valve, which resulted in a serious infection and removal of the patient’s infected heart valve. Following these disclosures, the impact of the market reaction was devastating as the market price of CryoLife’s common stock “dropped from a high of almost $45 per

129 See InterNet Bankruptcy Library, supra note 129.
130 See id.
131 See id.
133 See id.
134 See InterNet Bankruptcy Library, supra note 129; See The Law Offices of Berman DeValerio Pease Tabacco Burt & Pucillo, supra note 127 (describing a shareholders’ derivative suit filed against Cryolife alleging that the corporation violated FDA regulations and mishandled cadavers).
135 See InterNet Bankruptcy Library, supra note 129.
136 See id.
137 See id.
share..., and from $23.66 per share just before the disclosure to as low as $2.03 per share when the true facts became known.”

The undeniable power of the stock market and its associated public scrutiny may indirectly force corporations to exercise diligence. In addition, the continued scrutiny of both the media and the courts can enhance corporate accountability and ensure that improper behavior will not be swept under the rug. However, this indirect deterrence does not absolve courts and legislatures of their responsibility to preserve strong rights and new remedies for patients.

IV. PROPOSAL FOR NEW REMEDIES

A. New Remedies against Third Party Beneficiaries

Legislatures need to create a cause of action that will allow patients to recover based on a property interest in organs and cadavers, not simply for emotional distress caused by their use. The inadequacy of current remedies necessitates the development of new remedies for the misappropriation of organs. Lawmakers must develop clearly-defined remedies to compensate victims. Because of the seemingly intangible nature and value of human organs and tissue, it is informative to borrow from the remedial structure of intellectual property law.

In particular, one option to negotiate adequate compensation for organs may be borrowed from copyright law. In copyright law, copyrighted works may be licensed for a fixed compulsory licensing fee. Thus, in cases where third parties develop technology from organs, corporations could pay a mandatory licensing fee, based on the

138 See id.
139 See Stone, supra note 128, at 567.
141 See Gitter, supra note 26, at 270.
143 Id.
kind of technology developed and the organs used. Furthermore, trademark law also allows plaintiffs to recover a reasonable royalty, i.e. all or a percentage of the defendant’s profits. Similar to trademark law, plaintiffs in organ misappropriation cases could recover against third party corporate beneficiaries based on the defendant’s profits. Greater damages would not only sufficiently compensate victims in more egregious cases, but higher damages may act as a deterrent for such corporate misconduct. Under this scheme, damages could also take into account the contribution of the patient’s organ in the research, and be apportioned accordingly.

This policy could be expanded to create banks for legal acquisition of cell and tissue banks, which could greatly assist the progress of technology and destroy the need for “black market” acquisition of such tissue. This transparent and accessible scheme of compensation may also encourage tissue, cell, and organ donation.

B. Patent Law Reforms: Adoption of CBD proposals

Patent law has a profound impact upon research and development because it regulates the manner in which companies may exploit and develop their technology. Therefore, the USPTO has an ethical responsibility to the scientific community and the public. It is

146 Warren-Jones, supra note 148, at 100.
147 Cf. Goodwin, supra note 61, at 380 (“proscription on cadaver sales or grave robbing did not deter medical doctors from seeking sources upon which to experiment. Rather, as in the case of organs, it motivated a private industry.”).
148 See Warren-Jones, supra note 148, at 100 (proposing legal relief similar to copyright licensing).
149 See id. at 124 (proposing clearing houses for genetic information similar to those used for copyrighted musical works).
150 See Mary Taylor Danforth, Cells, Sales, & Royalties: The Patient's Right to a Portion of the Profits, 6 YALE L. & POL'Y REV. 179, 195 (1988); Thomas P. Dillon, Source Compensation for Tissue and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits, 64 NOTRE DAME L.REV. 628, 634. (1989); Goodwin, supra note 61, at 310 (discussing the need for greater transparency in incentive-based organ donation schemes).
152 United States v. Line Material, 333 U.S. 287, 320 (1948) ("But however that may be, the Constitution places the rewards to inventors in a secondary role. It makes the
important that the USPTO adopt CBD proposals requiring disclosure of
the origin of genetic resources and other biological materials in patent
applications.153 Two policies strongly support this shift: 1) improved
disclosure within the scientific and intellectual property communities;
and 2) increased public confidence and participation in the process of
organ donation.154

As for the first purpose, the Constitution provides one of the main
principles behind the patent system: the “promotion of the useful arts
and sciences.”155 For this reason, patent applicants must provide
sufficient descriptions in patent applications that fully disclose and
enable an invention.156 By requiring the disclosure of the origin of
genetic resources and biological materials, a patent applicant would
fully disclose the invention to the public, and further the knowledge of
the scientific community.157

Yet, there must be a system that will allow disclosure of a genetic
resource’s origin, while protecting the privacy of the family. One
solution to this problem would be a secure database of cadavers and
organs.158 In the event additional resources or samples are needed for
further research, a database and clearinghouse could also allow

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153 Nancy Kremers, supra note 94, at 143.
154 See id.
157 John Edward Schneider, Microorganisms And The Patent Office: To Deposit Or
Not To Deposit, That Is The Question, 52 FORDHAM L. REV. 592, 594 (“the
enablement requirement helps fulfill the overall purpose of the Act which is 'To
promote the Progress of Science and the useful Arts' by encouraging inventors
to share their acquired knowledge with the public.”); Sony Corp. of Am. v. Universal
City Studios, 52 U.S.L.W. 4090, 4093 (1984) (“[t]he purpose of the patent and
copyright laws is to motivate inventors and writers by granting them a limited
monopoly and to allow public access to the products of their genius when the
monopoly expires.”).
158 FOOD AND DRUG ADMINISTRATION, DRAFT PUBLIC HEALTH SERVICE GUIDELINE
ON INFECTIOUS DISEASE ISSUES IN XENOTRANSPLANTATION § 1.3.7, available at
http://www.fda.gov/ohrms/dockets/ac/00/backgrd/3571b1c.htm (last visited April 27,
2006) [hereinafter XENOTRANSPLANTATION]; see Michelle Locke, UC Considers
(last visited April 27, 2006) (after scandals involving the black-market sale of cadavers and organs, the University
of California is considering using barcodes to track cadavers).
scientists to indirectly contact families, while maintaining patient privacy. In a similar vein, the USPTO already has a depository of materials (such as starting materials and biological materials) for inventions if a patent applicant cannot readily describe how to make the material. The University of California has already proposed tracking cadavers by barcode or by radio frequency devices, which would facilitate an organ and cadaver database. There have also been proposals for the FDA to track organ donations.

As for the second purpose, this system would make the system of organ donation far more transparent. This transparency may foster more trust in the public; this element of trust is essential because the advancement of organ transplantation technology must be a joint venture between society and the biotechnology sector.

V. CONCLUSION

As research continues to progress, the need for human tissue and organs will only increase. With these increased needs, greater financial rewards increase in tandem with the possibilities of fraudulent acquisition and misappropriation of human tissue. Legislatures and courts must act now to define an authoritative and cohesive legal framework that balances patient rights and the requirements of scientific progress. Failing to change the murky status quo will undermine the goodwill of the scientific community and unnecessarily deter legitimate use of human tissue for important research.

As previously discussed, the Regents of University of California recently expressed interest in putting barcodes on cadavers to safeguard against further mishandling of cadavers. Undoubtedly, the comparison to consumer products cannot be avoided: this is indeed symbolic of the fact that organs and cadavers have become commodities within the research and scientific communities.

Yet when it comes to our legal framework providing protection for this most personal of commodities, courts and legislatures provide only a half-hearted protection of victim’s rights. It is especially ironic that cadavers lose their “personhood” and family rights to essentially

159 Warren-Jones, supra note 148, at 124.
160 37 C.F.R. § 1.801.
161 See Michelle Locke, supra note 162.
162 XENOTRANSPLANTATION, supra note 162 (recommending tracking for organ donors).
163 Id.
become property in some instances, but have no recognizable property right when victims of theft and misconduct involving tissue from cadavers seek remedies. No doubt much of the courts' motivation revolves around the negative moral and legal implications of treating organs as property or commodities. However, as we view the woefully inadequate remedies available for victims of fraudulent acquisition of organs and tissues, we must ask whether victims or unjust beneficiaries are benefiting more from a status quo in which a cadaver's only value is in the sum of its parts.